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STATUTORY INSTRUMENTS

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**2023 No. 314**

**The Medicines (Products for Human Use)  
(Fees) (Amendment) Regulations 2023**

**Amendment of Schedule 4**

**26.**—(1) Schedule 4 (periodic fees for licences) is amended as follows.

(2) In paragraph 5 (marketing authorisations), in column 2 (fee payable) of the table (periodic fees for holding a marketing authorisation)—

- (a) in entry 1, for “£9,710” substitute “£10,681”,
- (b) in entry 2, for “£307” substitute “£338”,
- (c) in entry 3(a), for “£9,710” substitute “£10,681”,
- (d) in entry 3(b)(i), for “£2,428” substitute “£2,671”,
- (e) in entry 3(b)(ii), for “£1,211” substitute “£1,332”,
- (f) in entries 3(b)(iii), (c) and (d), for “£307” substitute “£338”, and
- (g) in entries 3(e) to (h), for “£76” substitute “£84”.

(3) In paragraph 6 (marketing authorisation: where Part 2 of the Act applies), for “£307” substitute “£338”.

(4) In paragraph 7 (marketing authorisation: derivatives)—

- (a) in sub-paragraph (a), for “£9,710” substitute “£10,681”, and
- (b) in sub-paragraph (b), for “£6,554” substitute “£7,209”.

(5) In paragraph 11(1) and (2) (manufacturer’s licences or manufacturing authorisations), for “£468” substitute “£515”.

(6) In paragraph 12 (wholesale dealer’s licences)—

- (a) in sub-paragraph (1), for “£288” substitute “£317”, and
- (b) in sub-paragraph (2), for “£172” substitute “£189”.

(7) For paragraph 15(1), substitute—

“(1) The additional amount referred to in paragraphs 11(3) and 14 in relation to any fee period is—

- (a) the fee specified in the entry in column 2 of Table 1 (additional periodic fee in connection with notices for imported special medicinal products) corresponding to the estimated number of special import notices for that fee period specified in column 1, and
- (b) the fee specified in the entry in column 2 of Table 2 (additional periodic fee in connection with the number of different special medicinal products imported) corresponding to the estimated number of different special medicinal products imported for that fee period specified in column 1.

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*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

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**Table 1**

**Additional periodic fee in connection with notices for imported special medicinal products**

<i>Column 1</i>	<i>Column 2</i>
<i>Number of special import notices</i>	<i>Additional amount</i>
1 to 20	£70
21 to 100	£350
101 to 1,000	£2,400
1,001 to 5,000	£12,000
5,001 to 20,000	£30,000
20,001 to 50,000	£60,000
50,001 to 100,000	£120,000
100,001 or more	£200,000

**Table 2**

**Additional periodic fee in connection with the number of different special medicinal products notified for import**

<i>Column 1</i>	<i>Column 2</i>
<i>Number of different special medicinal products notified for import</i>	<i>Additional amount</i>
1 to 5	£100
6 to 10	£200
11 to 20	£400
21 to 50	£1,000
51 to 100	£2,000
101 to 200	£4,000
For each additional 100 special medicinal products notified for import above 200	£2,000"

(8) After paragraph 15(2), insert—

“(3) For the purposes of this paragraph, the estimated number of different special medicinal products notified for import for any fee period shall be the number notified in writing to the licence holder by the licensing authority before the start of that fee period as the number of such notices which the authority estimate will be given by the holder during the fee period.”.

(9) In paragraph 16 (traditional herbal registrations), for “£76” substitute “£84”.